IV.

(Obavijesti)

OBAVIJESTI INSTITUCIJA, TIJELA, UREDA I AGENCIJA EUROPSKE UNIJE

EUROPSKA KOMISIJA

Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. veljače 2017. do 28. veljače 2017.

(Objavljeno u skladu s člankom 13. ili člankom 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća ([1]))

(2017/C 102/01)

([1]) SL L 136, 30.4.2004., str. 1.

— **Izdavanje odobrenja za stavljanje u promet** (članak 13. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Prihvaćeno**

Datum odluke	Naziv lijeka	INN (medunarodni nezašticeni naziv lijeka)	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Farmaceutski oblik	Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova)	Datum obavijesti
13.2.2017.	LIFMIOR	Etanercept	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/16/1165	Prašak i otapalo za otopinu za injekciju	L04AB01	15.2.2017.
13.2.2017.	Olumiant	baricitinib	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/16/1170	Filmom obložena tableta	L04AA37	15.2.2017.
13.2.2017.	Vihuma	simoktokog alfa	Octapharma AB Lars Forssells gata 23, 112 75 Stockholm, Sverige	EU/1/16/1168	Prašak i otapalo za otopinu za injekciju	B02BD02	15.2.2017.
16.2.2017.	Alecensa	alektinib	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/16/1169	Kapsula, tvrda	L01XE36	20.2.2017.
17.2.2017.	Truxima	rituksimab	Celltrion Healthcare Hungary Kft. 1051 Budapest Bajcsy-Zsilinszky út 12., 4. em. 410, Magyarország	EU/1/16/1167	Koncentrat za otopinu za infuziju	L01XC02	22.2.2017.
27.2.2017.	Pregabalin Zentiva k.s	pregabalin	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/16/1166	Kapsula, tvrda	N03AX16	1.3.2017.

— **Izmjena odobrenja za stavljanje u promet** (članak 13. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Prihvaćeno**

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
6.2.2017.	Alimta	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/04/290	8.2.2017.
6.2.2017.	Amyvid	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/12/805	8.2.2017.
6.2.2017.	APTIVUS	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/05/315	8.2.2017.
6.2.2017.	Gardasil	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/06/357	8.2.2017.
6.2.2017.	Imvanex	Bavarian Nordic A/S Hejreskovvej 10a, DK-3490 Kvistgaard, Danmark	EU/1/13/855	8.2.2017.
6.2.2017.	Scintimun	CIS bio international Boîte postale 32, F-91192 Gif-sur-Yvette, France	EU/1/09/602	8.2.2017.
6.2.2017.	Silgard	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/06/358	8.2.2017.
6.2.2017.	Stribild	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/13/830	8.2.2017.
6.2.2017.	Tolucombi	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/13/821	9.2.2017.
6.2.2017.	Victrelis	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/11/704	8.2.2017.
8.2.2017.	Optruma	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/98/074	10.2.2017.
13.2.2017.	Aripiprazole Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/15/1009	15.2.2017.
13.2.2017.	Senshio	Shionogi Limited 33 Kingsway, London WC2B 6UF, United Kingdom	EU/1/14/978	15.2.2017.
13.2.2017.	Sustiva	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/99/110	15.2.2017.
16.2.2017.	Aripiprazole Sandoz	Sandoz GmbH Biochemiestrasse 10, A-6250 Kundl, Österreich	EU/1/15/1029	20.2.2017.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.2.2017.	Armisarte	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Íceland	EU/1/15/1063	20.2.2017.
16.2.2017.	Brimica Genuair	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/963	20.2.2017.
16.2.2017.	Docetaxel Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/611	20.2.2017.
16.2.2017.	Duaklir Genuair	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/964	20.2.2017.
16.2.2017.	Enyglid	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/580	20.2.2017.
16.2.2017.	EVOTAZ	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/15/1025	20.2.2017.
16.2.2017.	Farydak	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/15/1023	20.2.2017.
16.2.2017.	Forsteo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/03/247	20.2.2017.
16.2.2017.	Genvoya	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/15/1061	20.2.2017.
16.2.2017.	INOmax	Linde Healthcare AB SE-181 81 Lidingö, Sverige	EU/1/01/194	22.2.2017.
16.2.2017.	Irbesartan/Hydrochlorothiazide Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/583	20.2.2017.
16.2.2017.	Kadcyla	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/13/885	20.2.2017.
16.2.2017.	Kalydeco	Vertex Pharmaceuticals (Europe) Limited 2 Kingdom Street, London W2 6BD, United Kingdom	EU/1/12/782	20.2.2017.
16.2.2017.	Leganto	UCB Manufacturing Ireland Ltd Shannon Industrial Estate, Co, Clare, Ireland	EU/1/11/695	20.2.2017.
16.2.2017.	Mirapexin	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/97/051	20.2.2017.
16.2.2017.	Neupro	UCB Manufacturing Ireland Ltd Shannon Industrial Estate, Co, Clare, Ireland	EU/1/05/331	20.2.2017.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.2.2017.	Nimenrix	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/12/767	20.2.2017.
16.2.2017.	Nonafact	Sanquin Plasma Products B.V. Plesmanlaan 125, NL-1066 CX Amsterdam, Nederland	EU/1/01/186	20.2.2017.
16.2.2017.	Nucala	GlaxoSmithKline Trading Services Limited Currabinny, Carrigaline, County Cork, Ireland	EU/1/15/1043	20.2.2017.
16.2.2017.	Optimark	Mallinckrodt Deutschland GmbH Josef-Dietzgen-Strasse 1, D-53773 Hennef, Deutschland	EU/1/07/398	20.2.2017.
16.2.2017.	Portrazza	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/15/1084	20.2.2017.
16.2.2017.	Quinsair	Horizon Pharma Europe B.V. Naritaweg 165, NL-1043 BW Amsterdam, Nederland	EU/1/14/973	20.2.2017.
16.2.2017.	Ravicti	Horizon Pharma Ireland Limited Connaught House, 1st Floor, 1 Burlington Road, Dublin 4, D04 C5Y6, Ireland	EU/1/15/1062	20.2.2017.
16.2.2017.	Repaglinide Krka	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/579	20.2.2017.
16.2.2017.	Revlimid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/07/391	20.2.2017.
16.2.2017.	Revolade	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/10/612	20.2.2017.
16.2.2017.	Rivastigmine Actavis	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Íceland	EU/1/11/693	20.2.2017.
16.2.2017.	Sifrol	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/97/050	20.2.2017.
16.2.2017.	Stocrin	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/99/111	20.2.2017.
16.2.2017.	Twynsta	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/10/648	20.2.2017.
16.2.2017.	Viread	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/01/200	20.2.2017.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.2.2017.	Zyprexa Velotab	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/99/125	20.2.2017.
17.2.2017.	Caprelsa	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/11/749	21.2.2017.
17.2.2017.	Cyramza	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/14/957	21.2.2017.
17.2.2017.	Emend	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/03/262	21.2.2017.
17.2.2017.	IMBRUVICA	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/945	21.2.2017.
17.2.2017.	Pioglitazone Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/757	21.2.2017.
17.2.2017.	Pioglitazone Teva Pharma	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/758	21.2.2017.
17.2.2017.	Repatha	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/15/1016	21.2.2017.
23.2.2017.	Dacogen	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/12/792	27.2.2017.
23.2.2017.	Daklinza	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/14/939	27.2.2017.
23.2.2017.	Docetaxel Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/12/769	27.2.2017.
23.2.2017.	Docetaxel Kabi	Fresenius Kabi Oncology Plc. Lion Court, Farnham Road, Bordon, Hampshire GU35 0NF, United Kingdom	EU/1/12/770	27.2.2017.
23.2.2017.	Exviera	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/14/983	27.2.2017.
23.2.2017.	Harvoni	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/14/958	27.2.2017.
23.2.2017.	Ilaris	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/09/564	27.2.2017.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
23.2.2017.	Ketoconazole HRA	Laboratoire HRA Pharma 15 rue Béranger, F-75003 Pariz, France	EU/1/14/965	27.2.2017.
23.2.2017.	Lamivudine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/566	27.2.2017.
23.2.2017.	OLYSIO	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/924	27.2.2017.
23.2.2017.	Revlimid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/07/391	27.2.2017.
23.2.2017.	Sovaldi	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/13/894	27.2.2017.
23.2.2017.	Tivicay	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/13/892	27.2.2017.
23.2.2017.	Vargatef	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/14/954	27.2.2017.
23.2.2017.	Viekirax	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/14/982	27.2.2017.
23.2.2017.	Zinforo	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/785	27.2.2017.
27.2.2017.	Adcirca	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/08/476	1.3.2017.
27.2.2017.	Kisplyx	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom	EU/1/16/1128	1.3.2017.
27.2.2017.	Vectibix	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/07/423	1.3.2017.

— **Izdavanje odobrenja za stavljanje u promet** (članak 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Prihvaćeno**

Datum odluke	Naziv lijeka	INN (medunarodni nezašticeni naziv lijeka)	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Farmaceutski oblik	Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova)	Datum obavijesti
2.2.2017.	VarroMed	dihidrat oksalne kiseline/mravlja kiselina	BeeVital GmbH Wiesenbergstrasse 19, 5164, Seeham, Österreich	EU/2/16/203	Disperzija za košnice	Pending	6.2.2017.
9.2.2017.	Stronghold Plus	Selamektin/sarolaner	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/16/204	Otopina za nakapavanje	QP54AA55	13.2.2017.

— **Izmjena odobrenja za stavljanje u promet** (članak 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Prihvaćeno**

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
9.2.2017.	EQUIOXX	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/08/083	13.2.2017.
10.2.2017.	Vectormune ND	CEVA-Phylaxia Co. Ltd. Budapest, Szállás u. 5, 1107 MAGYARORSZÁG	EU/2/15/188	14.2.2017.
17.2.2017.	ERYSENG PARVO	Laboratorios Hipra, S.A. Avda. La Selva, 135, E-17170- Amer (Girona), España	EU/2/14/167	21.2.2017.
17.2.2017.	Trifexis	Eli Lilly and Company Ltd, Elanco Animal Health Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/13/155	21.2.2017.
17.2.2017.	Vectra 3D	CEVA SANTE ANIMALE 10 avenue de la Ballastière, F-33500 Libourne, France	EU/2/13/156	21.2.2017.
27.2.2017.	Equip WNV	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/08/086	1.3.2017.

Zainteresirane osobe koje žele na uvid dobiti javno izvješće o procjeni predmetnih lijekova i odluka koje se na njih odnose trebale bi se obratiti:

European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
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